
APPLICATION FOR UNITED STATES LETTERS PATENT

for

METHOD AND SYSTEM FOR TREATMENT OF ATRIAL
TACHYARRHYTHMIAS

by

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METHOD AND SYSTEM FOR TREATMENT OF ATRIAL
TACHYARRHYTHMIAS

Related US Application Data

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This application claims priority as a continuation application from US Serial No. 10/016,299, filed December 11, 2001, now pending.

Background of the Invention

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The present invention relates to surgical tools and procedures generally and relates more particularly to the use of ablation to create elongated lesions to treat atrial fibrillation or other medical conditions.

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In patients with chronic atrial fibrillation having tachycardia that resistant to medical treatment, the Maze III procedure has been employed. This procedure controls propagation of the depolarization wavefronts in the right and left atria by means of surgical incisions through the walls of the right and left atria. The incisions create blind or dead end conduction pathways, which prevent re-entrant atrial tachycardias from occurring. While the Maze procedure is successful in treating atrial fibrillation, the procedure is quite complex and is currently practiced by only a few very skilled cardiac surgeons in conjunction with other open-heart procedures. The procedure also is quite traumatic to the heart, as in essence the right and left atria are cut into pieces and sewed back together, to define lines of lesion across which the depolarization wavefronts will not propagate.

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It has been suggested that procedures similar to the Maze procedure could be instead performed by means of electrosurgical ablation, for example, by applying RF energy to internal or external surfaces of the atria to create lesions across which the depolarization wavefronts will not propagate. Such procedures are disclosed in US Patent No. 5,895,417, issued to Pomeranz, et al., US Patent No. 5,575,766, issued to

Swartz, et al., US Patent No. 6,032,077, issued to Pomeranz, US Patent No. 6,142,944, issued to Swanson, et al. and US Patent No. 5,871,523, issued to Fleischman, et al, all incorporated herein by reference in their entireties. Hemostat type electrosurgical or cryo-ablation devices for use in performing such procedures are described in US patent No. 5,733,280 issued to Avitall, US Patent No. 6,237,605 issued to Vaska, et al, US Patent No. 6,161,543, issued to Cox, et al., PCT published Application No. WO99/59486, by Wang and in pending US patent application SN 09/747,609 filed December 22, 2000 by Hooven, et al., all incorporated herein by reference in their entireties. In order for such procedures to be effective it is desirable that the electrosurgically created lesions are continuous along their length and extend completely through the tissue of the heart. In order for such procedures to be effective it is desirable that the electrosurgically created lesions are continuous along their length and extend completely through the tissue of the heart.

Summary of the Invention

According to a preferred embodiment of the present invention, a maze type procedure may be performed using one or more bipolar electrosurgical hemostats, which apply ablation energy (e.g. RF energy) across the walls of the left and right atria by means of delivery means (e.g. electrodes) located on either side of the atrial walls. In a preferred embodiment of the invention, the hemostats are provided with elongated R-F electrodes capable of assuming various straight and curved configurations. In the particular embodiment of the invention described herein, a bipolar electrosurgical hemostat is provided, shapeable, for example, to a set of configurations adapted to allow the physician to approximate the incisions that would occur during the Maze III procedure as described in the book 'Cardiac Surgery Operative Technique' by Donald B. Doty, M.D. at pages 410-419, incorporated herein by reference in its entirety, and hereafter referred to as the "Doty reference". Other curved configurations may also be accomplished, using the shapeable hemostat of the present invention, to allow approximation of the incisions that would be provided by other forms of the Maze procedure or to perform other ablation procedures.

The shapeable hemostat according to a preferred embodiment of the present invention is provided with elongated jaws that carry electrodes or other means for applying ablation energy to a patient's heart. The jaws of the hemostat may each carry a single, elongated electrode or may each carry a series of electrodes. While the preferred
5 embodiment of the invention as disclosed takes the form of a hemostat with R-F electrodes extending along both jaws, it is believed the invention may also usefully be practiced in a device having only a single elongated shapeable electrode or series of electrodes, for application of ablation energy to only the inner or outer surface of the wall of a heart chamber.

10 The jaws are fabricated of or provided with a core formed of a shape memory material, e.g. a nickel titanium alloy such as Nitinol, a copper-nickel aluminum or copper zinc aluminum alloy (SME brass) or a plastic having shape memory properties. If the shape memory material is not itself biocompatible, it should be encased in a
15 biocompatible covering, e.g. encapsulated within the material of the jaws. The material chosen preferably displays its memorized configuration at a temperature above the temperature to which it will be heated during the ablation procedure. This temperature will be dependant on the construction of the jaws of the hemostat, and will vary depending on the degree of thermal insulation between the electrode and the
20 shape memory material. If the electrode itself is the shape memory component, then the transition temperature should be above 50 degrees Celsius. In any case, the transition temperature should be well above body temperature. The transition temperature should be below the temperature to which it will be heated to resume its memorized configuration, e.g. less than 100 degrees Celsius, if heated using boiling
25 water, above 100 degrees Celsius if placed in a heater. The specific composition of the alloy or plastic material can be chosen to control transition temperature, using standard techniques. The jaws of the hemostat may thereby be shaped at room temperature and will retain their shape during subsequent use in the body to ablate tissue. The memorized configuration may be straight or curved.

In use, the jaws of the hemostat are shaped manually or with the use of a bending fixture to exhibit a desired configuration for use in producing a particular lesion. As noted above, these lesions may be produced as part of a procedure corresponding to a Maze type procedure. After the lesion is produced, the shape memory material in the jaws of the hemostat is heated to a temperature above its transition temperature so that the jaws return to their memorized configuration and may then either be used in this configuration to produce the next lesion or may be again shaped to an alternative desired configuration. This process is continued until all desired lesions have been produced. Because the jaws are returned to their memorized configuration, e.g. straight, before reshaping, any kinks or curves resulting from the previous reshaping will be eliminated. This allows the jaws to be successively reshaped, with subsequent reshapings unaffected by previous reshapings.

The jaws may be heated by any convenient means, for example by placement in hot water, placement in or on an electric heater, or by means of resistive heaters built into the jaws themselves. The configurations assumable by the hemostat jaws may be straight, curved or bent, adapted to an individual patient according to the judgment of the physician. Alternatively, the physician may be provided with a set of bending fixtures to provide a pre-determined set of curved configurations, each configuration associated with one or more of a predetermined set of desired lesions.

The particular embodiment of the invention as disclosed herein is described in the context of hemostats particularly adapted for treatment of atrial fibrillation during open chest surgery, with the patient undergoing cardiopulmonary bypass. However, the present invention is also believed applicable to closed chest procedures, in which the heart is observed thoroscopically and access is provided by means of thoroscopic surgical ports. It is believed the invention is also applicable to other procedures involving creation of a set of elongated lesions in heart tissue or elsewhere in the body.

A Brief Description of the Drawings:

Figure 1A illustrates an electrosurgical hemostat according to the present invention having two elongated jaws that exhibit a memorized, generally straight configuration.

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Figure 1B illustrates an alternative configuration for the tips of the jaws of the hemostat illustrated in Figure 1A.

Figures 2A, 2B, 2C, 2D and 2E all illustrate cross section through alternative embodiments for the jaws of the hemostat otherwise as illustrated in Figure 1A.

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Figure 3 illustrates a side view of an electrosurgical hemostat according to the present invention, shaped to display a bent configuration.

Figure 4 illustrates a side view of an electrosurgical hemostat according to the present invention, shaped to display a first, curved configuration.

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Figure 5 illustrates a side view of an electrosurgical hemostat according to the present invention, shaped to display a second, curved configuration.

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Figures 6A, 6B and 6C illustrate operation of a first bending fixture according to the present invention.

Figures 7A, 7B and 7C illustrate operation of a second bending fixture according to the present invention.

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Figures 8A and 8B illustrate operation of a third bending fixture according to the present invention.

Figures 9A through 9M are a series of drawings illustrating schematically a surgical procedure performed using an electrosurgical hemostat according to the present invention and illustrating schematically the various incisions and lesions produced.

5 Detailed Description of the Preferred Embodiments

10 The embodiment of the invention as disclosed in the present application includes a shapeable electrosurgical hemostat and mechanisms for causing the jaws of the hemostat to assume predetermined configurations particularly adapted to perform an ablation procedure modeled on the Maze III procedure as described in the Doty reference, cited above. Within the context of the invention, however, other predetermined sets of configurations may be substituted and/or the physician may simply manually shape the jaws of the electrodes to his liking. The set of configurations is described in more detail below.

15 Figure 1A illustrates a top plan view of a hemostat provided according to the present invention. The hemostat may be approximately 31 centimeters in overall length as illustrated at B2, with jaws of approximately 8 centimeters in length, as illustrated at A1. The hemostat includes two elongated handle members 12 and 14, each provided with a finger loop at its proximal end. A conventional hemostat locking mechanism 14 is also provided. The handles of the hemostat may be fabricated of stainless steel or other readily resterilizable material. Alternatively, the handles 11 and 12 might be fabricated of a biocompatible plastic and/or the hemostat may be disposable.

25 To the jaws 18 and 19 of the hemostat extend distally from the pivot or hinge 16, and carry elongated electrosurgical electrodes 24 and 25. When the jaws are parallel to one another, electrodes 25 and 25 are preferably spaced approximately 0 to 7 mm from one another, more preferably 1 to 5 from one another, to facilitate uniform contact along opposite sides of a patient's atrial wall. In use, the atrial wall is compressed
30 between electrodes 24 and 25, and R-F energy is applied between the electrodes in order to create an elongated continuous lesion extending through the cardiac tissue.

Using the hemostat as configured in Figure 1A, a linear lesion is produced. In the particular embodiment illustrated, the jaws exhibit a memorized, generally straight configuration.

5 The electrodes 24 and 25 are preferably configured to allow fluid – assisted cardiac ablation, of the type generally described in US Patent No. 6,096,037 issued to Mulier, incorporated herein by reference in its entirety. To this end, each of the electrodes is provided with an electrical conductor, 20, 23, allowing delivery of R-F electrical energy to the electrodes 24 and 25, respectively and with a fluid lumen 21, 22,
10 allowing for delivery of saline solution or other conductive fluid to and along the length of electrodes 24 and 25. If resistive heaters are included, arranged along the length of the jaws 18, 19, additional conductors 20A and 23A are provided in order to power the heaters. Various alternative embodiments of the electrodes and jaws of the hemostat of Figure 1A are illustrated in Figures 2A through 2D, discussed below.

15 In use in a preferred embodiment of the invention, one jaw of the hemostat of Figure 1A is inserted into the interior right or left atrium through an incision provided in the wall of the left or right atrium, while the other jaw remains outside of that chamber. The jaws are pressed together, somewhat compressing the atrial wall between the
20 jaws, to provide for continuous contact along the length of the jaws on both sides of the atrial wall. The ablation jaws in some cases may instead be arranged along opposing external surfaces of an organ, for example opposite sides of an atrial appendage or along opposite sides of the tissue adjacent the bases of the right or left pulmonary veins.

25 RF energy is delivered between the electrodes. Delivery of energy or power to assure a complete lesion may be accomplished by measurement of impedance between the electrodes, as in US Patent No. 6,133,592, issued to Taylor, US Patent No. 5,718,701, issued to Shai, et al or US patent No. 5,357,956, issued to Nardella, or allowed
30 Pending US Application No. 09/347,635, filed July 6, 1999 by Hoey et al, all incorporated herein by reference in their entireties. Alternatively, thermocouples or

other temperature sensors may be added to the jaws of the hemostat and delivery of energy or power controlled as in US Patent No. 5, 685,878, issued to –Falwell, et al., US Patent No. 6,045,550, issued to Simpson, et al., US Patent No. 5,688,267, issued to Panescu, et al or US patent No. 5,596,995, issued to Sherman, et al., all also incorporated herein by reference in their entirety. As an additional alternative, delivery of energy or power may be time terminated, based upon empirically determined times found to lesions extending completely through the atrial walls at the power or energy levels chosen, or regulation of ablation energy by means of any of the references cited above may be employed if appropriate.

It is anticipated that in some versions of the present invention which employ a more limited access approach to the heart, the distal tips of hemostat jaws themselves may be sharpened and used to pierce the atrial wall, eliminating the necessity of a separate incision. Figure 1B illustrates such an alternative hemostat jaw construction, wherein hemostat jaws 18A and 19A correspond generally to jaws 18 and 19 in Figure 1A, and carry electrodes 24A and 25A which also correspond to electrodes 24 and 25 in Figure 1A. However, the distal tips 15 and 17 of the jaws are sharpened to a point or an edge so that either may be used to directly penetrate the atrial wall, eliminating the necessity of a separate incision.

Figures 2A through 2E are cross sectional views through the jaws of a hemostat as in Figure 1A, illustrating possible alternative constructions. In Figure 2A, the jaws 18 and 19 are made of metallic cores 26, 28, of shape memory metal such as Nitinol, covered by insulative coatings or paint, 27, 29. Resistive heaters 34 and 35 are optionally provided, extending along the cores 26, 28. Electrodes 24 and 25 take the form of elongated conductive coils, 30A, 33A, carrying tubes 31A, 32A, of expanded PTFE, through which a conducted fluid such as saline solution may be delivered along the length of the electrode coils 30A, 33A. The lumens of the EPTFE tubes 31A, 32A may be sealed at their distal extremities.

Figure 2B illustrates a first alternative embodiment, corresponding generally to that illustrated in Figure 2A, with identically numbered elements corresponding to those illustrated in 2A. In this embodiment, the configuration of the conductive coil, 31B, 32B and the expanded PTFE tubes, 32B, 33B is reversed, so that the coils are located within the EPTFE tubes. As in the embodiment illustrated in Figure 2A, saline or other conducted fluid is delivered through the inner lumen of EPTFE tubes 32B, 33B. Resistive heaters are not included, so heating of the hemostat to resume its memorized configuration must be accomplished using other means, such as placing the jaws of the hemostat in a vessel filled with hot water, or into or on an electric heater.

Figure 2C illustrates a third embodiment according to the present invention. In this case, elements correspond to identically numbered elements in Figure 2A. However, in the embodiment of Figure 2C, the jaws 18, 19, take the form of molded plastic members with cores formed of shape memory metal rods 36, 37.

Figure 2D illustrates a fourth embodiment according to the present invention.. Elements correspond to identically labeled elements in Figure 2A. In this embodiment, the jaws 18, 19 are molded plastic members and the electrodes 24, 25 take the form of tubes of shape memory metal, provided with a series of holes 41, 42, open to the lumen of the tube. In this embodiment, conductive fluid is delivered through the lumen of the tube and to the tissue through the holes 41, 42, and no separate fluid delivery tube is required.

Figure 2E illustrates a fifth embodiment according to the present invention.. Elements correspond to identically labeled elements in Figure 2A. However, in the embodiment of Figure 2E, the jaws 18, 19, take the form of molded plastic members with cores 38, 39, formed of shape memory metal. Cores 38 and 39 are rectangular in cross section, encouraging bending of the jaws in parallel planes. This feature may be particularly desirable if bending of the jaws manually, without bending fixtures, is to be performed.

Figures 3 – 5 illustrate various curved and bent configurations of the hemostat of Figure 1A, adapted to perform an ablation procedure analogous to the Maze III procedure. While electrodes are not illustrated in these figures, they should be understood to be present and to correspond with those illustrated in Figures 2A – 2E. Similarly, While conductors and fluid lumens are not illustrated in Figures 3 - 5, they should be understood to be present and correspond to those as illustrated in Figure 1A.

Figure 3 illustrates a side view of the hemostat of Figure 1A wherein the jaws 18 and 19 are shaped to describe a generally straight distal portion extending over a length E2, which may be, for example, 5 ½ centimeters. The jaws are bent at C2 around a radius of approximately .5 centimeters and describe an angle D2 of approximately 60 degrees, as illustrated.

Figure 4 illustrates a side view of the hemostat of Figure 1A wherein the jaws 18 and 19 are shaped to define a distal, generally straight portion E3 extending for approximately 2 centimeters, and are curved around a radius C3 of approximately 3 centimeters, to define an angle D3 of approximately 65 degrees.

Figure 5 illustrates a side view of the hemostat of Figure 1A wherein the jaws 18 and 19 are shaped to define a generally straight distal portion extending over a length E4 of approximately 3 centimeters, and curved around a radius C4 of approximately 5 centimeters to define an angle D5 of approximately 60 degrees.

Figures 6A, B & C illustrate a first fixturing system for bending jaws of a hemostat as illustrated in Figure 1A to assume a desired curved configuration. The apparatus illustrated in Figures 6A through 6C is intended to assure that the jaws assume the desired curved configurations and that they also remain parallel to one another, facilitating their use to provide bipolar ablation along the entire length of the electrodes on the jaws.

Figure 6A shows the first component 600 of the fixturing system in side view, with jaw 19 of the hemostat of Figure 1A visible mounted within the component. The component includes a flexible backbone 620, for example, fabricated of spring steel, to which a series of upwardly extending members 602, 604, 606, 608 are mounted. Each of these members, 602, 604, 606 and 608 is one of a set of three members arranged to engage both jaws of the hemostat and retain them in a parallel configuration. Each of the members is provided with a hole 610, 612, 614 for engaging a pin on the second component of the fixturing system, discussed below in conjunction with Figure 6C.

Figure 6B illustrates a cross-sectional view through the first component 600 of the fixturing system illustrating upwardly extending member 604 and its corresponding associated upwardly extending members 622 and 624. Members 604, 622 and 624 together define two openings, which receive the jaws 18 and 19 of the hemostat as illustrated. Members 604, 622, 624 may be spread apart from one another slightly, due to the resilience of the base member 620, to allow insertion of the jaws 18 and 19 of the hemostat. Members 622 and 624 are provided with holes, 626 and 628, aligned with hole 612 in member 604.

Figure 6C illustrates the second component of the fixturing system, comprising a metal plate 630 having a plurality of holes arranged corresponding to desired curved configurations to be displayed by the hemostat jaws. As illustrated, pins 632, 634, 636, and 638 are inserted in one set of holes to define a first curved configuration. Unused holes 640, 642, and 646 are employed to create alternative curved configurations.

In use, the first component 600 of the fixturing system, mounted to the jaws 18 and 19 of the hemostat is fitted to the second component 630 by bending the jaws of the hemostat so that the pins 632, 634, 636 and 638 pass through the holes defined in the upwardly extending members, assuring the displayed curvature of the hemostat is as desired.

The hemostat is then removed from the fixturing member and employed to create a lesion having a configuration corresponding to the provided curvature. After creation of the lesion, if the configuration of the hemostat is to be altered before the next lesion is produced, it is heated to cause it to resume its original memorized configuration, for example, a straight configuration as illustrated in Figure 1A. The hemostat may be used to create a lesion in this configuration or may be reshaped to display a different curved configuration using the fixture system.

The advantage of the step of heating the hemostat jaws to assume their previous memorized confirmation as opposed to simply re-bending the jaws to assume a second curved configuration is that it eliminates any set bends or kinks that might interfere with the jaws assuming their desired new configuration. For example, if the jaws have been shaped to provide the sharply bent configuration illustrated in Figure 3, re-bending the jaws to assume a smoothly curved configuration as in Figures 4 and 5 would otherwise be difficult in view of the tendency to the jaws to retain the small radius bend as illustrated in Figure 3. Similarly, returning the jaws to a straight configuration simply by attempting to re-bend the jaws may be difficult due to the tendency of the jaws to retain their previously imparted curved configuration.

Figures 7A through 7C illustrate a second fixturing system which may be used to impart desired predefined curves or may be used to assist the physician in providing manually shaped curves while retaining the jaws of the hemostat in a parallel configuration. The fixturing system of Figures 7A through 7C includes a first component 700 as illustrated in Figure 7A. This first component includes a flexible base member 720, which may be fabricated of spring steel or other flexible material having a strong tendency to bend only in a single plane. Attached to base member 720 is a coil 722 having an interior lumen specifically configured to receive the two jaws 18 and 19 of the hemostat. As illustrated, jaw 19 as visible inserted into the coil 722.

Figures 7B illustrates the first component of the fixturing system in cross section. In this view it can be seen that the coil 722 provides a generally rectangular internal lumen in which the jaws 18 and 19 of the hemostat are mounted. Individual coils are provided with a depression 724 which defines the desired spacing between the jaws during the bending operation. With this fixture attached to the jaws, the physician may bend the jaws manually, assuring that they remain in a parallel configuration. After bending, the first component of the fixture is simply removed from the jaws by sliding it off the distal ends of the jaws.

Alternatively, the first component 700 may be used in conjunction with a second fixturing component 730 to provide a predefined curve. Fixturing component 730 is provided with two generally straight recesses 732 which have a depth adapted to provide any desired straight distal portion of the jaws as configured. For example, the depths of the recesses 732 and 734 may correspond to lengths of the straight portions E2, E3, or E4, as illustrated in Figures 3, 4 and 5 respectively. The second component 730 of the fixturing system includes a defined curved surface 736, around which the first fixturing component 700, carrying the jaws 18 and 19 of the hemostat, is bent to provide a defined curvature corresponding to the curvature of the surface 736.

In this fixturing system, it is envisioned that several components to similar to component 730, each having a different defined curved surface and recesses of differing depths for receiving the distal ends of the hemostat jaws may be provided to provide a family of desired curved configurations.

Figures 8A and 8B illustrate a third fixturing system, employing fixturing components similar to fixturing components 730, illustrated in Figure 7C. In this system, however, no restraining devices are mounted to the jaws of the hemostat to be reshaped, simplifying the process. Fixturing component 800 is provided with two inwardly extending recesses 802 and 804, corresponding generally to recesses 732 and 734 in the fixturing component illustrated in Figure 7C. In a similar fashion, they are

provided with a depth that corresponds to the length of any straight, distal portion desired for the jaws. In addition, the component 800 is provided with two grooves 806 and 808, extending along a desired curvature for the hemostat. A raised portion 810 separates the grooves and defines the desired inter-jaw spacing during the bending operation. The combination of the recesses 802, 804, the grooves 806 and 808 and the raised portion 810 provide a mechanism for retaining the jaws in a parallel configuration while bending them to assume the desired curvature.

Figure 8B illustrates the jaws 18 and 19 of the hemostat inserted into the recesses 802 and 804 of the fixturing component 800, and bent around the component, arranged within the grooves 806 and 808. After bending, the hemostat is simply removed from the fixturing component 800 and may be employed to create the lesion having a configuration corresponding to the curvature provided by the fixturing component 800. In this embodiment of the invention, a set of components similar to fixturing 800 would be provided, each having recesses of a desired depth to define any straight distal portion of the jaws, and having grooves extending around a predefined desired curvature to define the curved portion of the jaws.

In the discussion of the various bending and fixturing systems above, it is assumed that the memorized configuration of the hemostat jaws is a straight configuration. In conjunction with the procedure defined below, as many of the lesions are performed using the jaws in this straight configuration, this is probably the most desirable embodiment. However, in other procedures, it may be desirable to employ a memorized configuration that has a preset curve, if this curved configuration is used for a substantial portion of the lesions to be performed. In this case, the fixturing devices as illustrated in Figures 6A - 8B may be modified to provide a mechanism for bending the hemostat jaws to assume a straight configuration. In all of the embodiments in Figures 6A through 8B, it should be understood that the curvature defined by the fixturing mechanism is preferably is somewhat greater than the ultimately desired curvature, due to the fact that some elastic rebound of the hemostat jaws after bending is to be expected. As such, each fixture must be designed to

provide for some degree of over-bending as compared to the desired ultimate configuration. A specific degree of over-bending provided by any particular fixture will, of course, be a function of the specific shape memory material chosen and of the specific configuration of the shape memory material.

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It should also be noted that in the above discussion of the procedures associated with heating the forceps to allow them to assume their memorized condition, the heating step is generally conceived of as occurring external to the body, as a relatively elevated temperature may be generally be required. However, in some cases, it is possible that the step of heating the forceps jaws might occur internal to the patient's body, for example, in those embodiments in which resistive heaters are provided, extending along the jaws. In these cases, it is envisioned that the hemostat might remain within the patient's body while electrical power is applied to cause the resistive heaters to in turn cause the hemostats to resume to their memorized straight or curved configurations.

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Figures 9A - 9M are schematic drawings which illustrate a procedure performed using the bipolar electrosurgical hemostats described above to obtain a result analogous to the Maze III procedure as described in the Doty reference cited above. The lesions produced using the hemostats correspond to incisions as described in this reference, and the correspondence of the lesions to the incisions is described below.

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Figure 9A is a schematic drawing illustrating the structure of the right and left atria, 500, 502, respectively, as viewed from a lower aspect, including tricuspid valve 16 and mitral valve 14 and as viewed from a more superior aspect, including the bases of the pulmonary veins 512 and the bases of the superior vena cava and inferior vena cava, 508 and 510 respectively, which enter the right atrium 500. The right and left atrial appendages are also illustrated schematically at 504 and 506, respectively. The structures as illustrated in Figure 9A are correspondingly numbered in Figures 9B - 9M below.

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For purposes of understanding the basic method of the present invention as illustrated, it should be assumed that the operation is undertaken as an open chest operation, with the heart stopped and the patient on full bypass. Modifications to the procedure, in case of a limited access, stopped heart procedure and/or a limited access, beating heart procedure, are also generally described. Figure 9B illustrates the first step of the procedure, comprising removal of the right atrial appendage 504. Right atrial appendage 504 is removed by means of an incision 507, which may be made by means of a scalpel or scissors. In a context of a closed chest procedure on either a beating or a stopped heart, a thoracoscopic tool may be substituted, preferably one capable of simultaneously cutting and stapling the remnant of the right atrial appendage.

Figure 9C illustrates the second step of the procedure, as performed using an open chest approach. During the second step, the electrosurgical hemostat of the present invention, with the jaws in the straight configuration as illustrated Figure 1A, with one jaw 19 of the hemostat inserted into the right atrium through the opening left by removal of the right atrial appendage and the other jaw 18 arranged along the exterior surface of the heart. Jaws 18 and 19 are inserted until they extend to a point 520 located approximately at the mid point of the right atrium, approximately 5 centimeters from the opening 505 left by removal of the right atrial appendage. The jaws 18 and 19 are compressed and RF energy is applied between the electrodes located in jaws 18 and 19 to create an elongated lesion, extending through the tissue of the right atrial wall, to provide a block against passage of depolarization waves there across. For purposes of the following drawings, the placement of various hemostats will be described, but now specifically illustrated. Instead, the lesions to be produced by the hemostats will be illustrated by means of beaded lines, so that their interconnection and their relationship to the structures of the left and right atria 502, 500, may be understood. It should be understood that the hemostats are to be placed with their jaws extending along the lesions as illustrated, unless otherwise specified.

In closed chest, limited access procedures, it is anticipated that the lesion produced may be made by inserting the jaw of an electrosurgical hemostat as illustrated in

conjunction Figure 1A, but having a sharpened tip as illustrated in Figure 1B, directly through the heart wall at point 520, and the jaws advanced to the sealed remnant of the removal of the right atrial appendage to define a corresponding lesion.

5 Figure 9D illustrates the next step in the procedure and also illustrates lesion 522 produced by the application of the electrosurgical hemostat with jaws retaining the straight configuration as illustrated in Figure 1A. Lesion 522 corresponds generally to the incision illustrated at step A1 as described in the Doty reference. At 524, a local access incision is cut, at a point approximately midway between the inferior vena cava and superior vena cava (510, 508). Lesions 526 and 528, extending from access
10 incision 524 to the superior and inferior vena cava, respectively, are produced by inserting one jaw of a hemostat as illustrated in Figure 1A through the access incision 524 and arranging the jaws of the hemostat to extend on either side of atrial tissue from the incision 524 to the superior vena cava and inferior vena cava, respectively.
15 Alternatively, the jaws of the hemostat may be configured as illustrated in Figure 3. The lesions 528 and 526 so produced correspond to the incisions illustrated at step B as described in the Doty reference. In more limited access surgeries, hemostats having sharpened jaws as illustrated in Figure 1B might be employed, with the sharpened tip of a jaw employed to create the access incision 524.

20 Figure 9E illustrates the next step in the procedure. In this step, one jaw of the hemostat, having a configuration as illustrated in Figure 1A or Figure 3 is inserted through access incision 524, and the jaws are arranged along either side of the atrial wall to create lesion 530, extending to the annulus of tricuspid valve 516, terminating
25 at a point 534 approximately at the center of the posterior leaflet 532. This lesion should extend as close as possible to the tricuspid annulus. This lesion corresponds generally to the incision illustrated at steps D and E as described in the Doty reference. Optionally, cryo-ablation may be performed at the tricuspid annulus at the terminus of lesion 530, by means of a cryo-probe inserted through the opening 505 in
30 the remnant of the right atrial appendage. Cryo-ablation corresponds generally to that illustrated at step F as described in the Doty reference. In more limited access

surgeries, the cryo-probe might be inserted through access lesion 524 or might be inserted transvenously.

Figure 9F illustrates the next step of the procedure. In Figure 9F, lesion 536 is created using the distal portion of the jaws of a hemostat configured as in Figure 1A. One jaw of the hemostat is inserted through the opening 505 in the remnant of the right atrial appendage, and the jaws are arranged to extend along either the right atrial wall to the annulus of the tricuspid valve 516 at the midpoint of the anterior leaflet 538. This lesion corresponds generally to the incision illustrated at steps H and I as described in the Doty reference. Care must be taken during this step to avoid the right coronary artery. Optionally, cryo-ablation may be applied at the tricuspid annulus at point 540, at the termination of lesion 536. Again, cryo-ablation may be provided by means of a cryo-probe inserted via the opening 505 in the remnant of the right atrial appendage, through access lesion 524, or, alternatively be means of a cryo-probe inserted transvenously. Cryo-ablation corresponds generally to that illustrated at step J as described in the Doty reference.

Figure 9G illustrates the next step of the procedure which is the creation of an incision 542 extending through the left atrial wall, posterior to the inter atrial groove, near the orifices of the right pulmonary veins. In an open chest procedure, incision 542 may be made conventionally by means of scissors or a scalpel. Incision 542 corresponds to the incision illustrated at step K as described in the Doty reference. In more limited access surgeries, incision 542 might be replaced by a simple access incision made by means of the sharpened tip of one of the jaws of the hemostats used to create the lesions surrounding the orifices of the pulmonary veins, as discussed below.

Figure 9H illustrates the next step of the procedure, which is the creation of lesions 543 and 546. Lesions 543 and 546 may be accomplished by insertion of the hemostat having jaws re-shaped to the curved configuration as illustrated in Figure 5, reversing the orientation of the hemostat between lesions, to create two curved lesions extending around the base of the pulmonary veins 512 and meeting at a point 544, to

complete the lesion path. Lesions 543 and 546 correspond generally to the incisions illustrated at steps L and N as described in the Doty reference. In an alternative procedure, lesions approximating the incisions illustrated at steps L and N may be produced by compressing the atrial wall tissue adjacent the bases of the left pulmonary veins between jaws of the hemostat illustrated in Figure 4A or 5A applied epicardially to produce a lesion encircling the bases of the left pulmonary veins and repeating the procedure to correspondingly produce a lesion encircling the bases of the right pulmonary veins.

Figure 9I illustrates the next step of the procedure, in which the hemostat is reshaped to display the more sharply curved configuration as illustrated in Figure 4 is employed to create lesion 548. Lesion 548 is created by inserting one jaw of the hemostat, into incision 542, the other into access incision 524, and compressing the atrial septum therebetween. The jaws are arranged so that they define a curved lesion extending along the atrial septum, extending to a point above the fossa ovalis, near but not into the tendon of Todaro. As the atrial septum is not visible in Figure 9I, lesion 544 should be understood to correspond to the incision illustrated at step M as described in the Doty reference.

Figure 9J illustrates the next step in the procedure, comprising the removal of left atrial appendage 506 by means of an incision 550. In open chest procedures, this incision might be made by means of a scissors or scalpel. In more limited access surgeries, this incision might be made by means of a thoroscopically introduced, preferably one capable of simultaneously cutting and stapling the remnant of the right atrial appendage.

Figure 9K illustrates the next step of the procedure, comprising the creation of lesion 552. Lesion 552 may be created using the hemostat reshaped to display the more gently curved configuration illustrated in Figure 5 to create a curved lesion departing from lesion 546 and extending to the opening 550 in the right atrial appendage. As

with lesions 543 and 546, the lesion may be produced by inserting one jaw of the hemostat through the incision 542, and compressing the left atrial wall between the jaws of the hemostat. Lesion 552 might also be performed prior to removal of the left atrial appendage, in conjunction with creation of lesions 543 and 546. In some
5 embodiments of the invention, lesion 542 might be replaced by a simple incision extending from the opening 550 of the remnant of the left atrial appendage, and then later repaired by suture

Figures 9L illustrates the next step of the procedure, comprising the creation of lesion
10 558. Lesion 558 is created using the hemostat configured as in Figures 5, one jaw being inserted through incision 542 and compressing the left atrial wall between the jaws of the hemostat to create a lesion extending from lesion 543 to the mid point 560 of the annulus of the posterior mitral valve. Lesion 558 corresponds to the incision illustrated at step S as described in the Doty reference. Care must be exercised during
15 this incision to prevent damage to the circumflex artery and the coronary sinus. Optionally cryo-ablation may be provided at the mid-point 560 of the posterior mitral valve annulus, by means of a cyro-probe introduced through the opening 550 through the remnant of a left atrial appendage, or through incision 542. In more limited access surgeries, cryo ablation may be provided by means of transvenous cyro-ablation
20 catheter. Cryo-ablation corresponds generally to that illustrated at step J as described in the Doty reference.

Figure 9M illustrates the final steps of the procedure, comprising closing of the openings 505 and 550 into the remnants of the right and left atrial appendages,
25 respectively, by means of sutures 554 and 556. As noted above, in the event that thoracoscopic surgical implements are employed, these openings may have previously been closed in conjunction with their creation, by means of staples, or otherwise, by means of thoracoscopic surgical tools. In addition, incision 542 is shown as closed by means of sutures 560 as discussed above, in some embodiments, incision 542 may
30 have been replaced by simple puncture incision, which might be closed by means of

staple, sutures, or otherwise, applied thoracoscopically. Access in incision 524 is similarly closed at this time.

5 The hemostat as illustrated in Figures 1A through 5, discussed above, has the general configuration of a conventional hemostat, as would be employed in the context of an open chest procedure. In the event that the procedure is adapted to a thoracoscopic procedure, similarly configured hemostat jaws may be employed on a thoracoscopically introduced instrument to create the various lesion patterns. Modifications to the specific configurations of the disclosed hemostat may be desirable in conjunction with adapting the hemostat to thoracoscopic use or in 10 conjunction with adapting the hemostat set to other versions of the Maze or Maze type procedures or to procedures performed elsewhere on the heart or other organs. Such modifications are believed to be within the scope of the invention.

15 While the hemostat disclosed in the present application is preferably provided with R-F electrodes to create elongated lesions, it is believed the invention may also usefully be practiced in conjunction with hemostats employing microwave, heat, cyro-ablation or other ablative techniques to create the various lesions provided by the method. Further, while the hemostats disclosed in the present application are provided with a single elongated electrode extending along each jaw, embodiments in 20 which multiple electrodes arrayed along each jaw are employed are also believed useful in practicing the invention. Further yet, as noted above, the present invention is also believed useful in the context ablation devices employing only a single elongated, electrode or a single series of electrodes.

25 Therefore, the above disclosure should be considered as exemplary, rather than limiting, with regard to the following claims.

In conjunction with the above specification, we claim: